

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION**

UNITED STATES OF AMERICA)
Plaintiff,)
Brought by Gary L. Hampton Whistleblower)
v.) Case No. 07-00489-CV-W-JTM
ALPHAPOINTE ASSOCIATION FOR) UNDER SEAL
THE BLIND) JURY TRIAL DEMANDED
Defendant.)
COMPLAINT

COMPLAINT

For its complaint, the United States of America alleges:

JURISDICTION AND VENUE

1. Jurisdiction is founded on the False Claims Act, 31 U.S.C. §3732 and under 28 U.S.C. §§ 1331, 1345.
2. Venue is proper in the Western District of Missouri under 28 U.S.C. 1391(b)(c) and under 31 U.S.C. §3732(a). This court has personal jurisdiction over the Defendant because they reside and transact business within this District.

THE PARTIES

3. Plaintiff in this action is the United States of America (“United States”).
4. Defendant, Alphapointe Association for the Blind (“Alphapointe”) is a non-profit Missouri corporation that manufactures and provides plastic pharmaceutical bottles to the United States Department of Veteran’s Affairs and other

government entities. Defendant's principal place of business is located at 7501 Prospect, Kansas City, Missouri 64132.

GENERAL ALLEGATIONS

5. This is an action for damages and civil penalties under the False Claim Act, 31 U.S.C. §§ 3729-3733, as amended, against the above named defendant for money damages and civil penalties arising from the presentation of false and fraudulent claims to the United States Department of Veteran Affairs (hereinafter VA).
6. The False Claims Act provides, *inter alia*, that any person who knowingly submits a false or fraudulent claim to the federal government for payment or approval is liable to the Government for civil penalty of not less than \$5,500 and not more than \$11,000 for each claim. 31 U.S.C. 3729(a). Suits brought under the Act may include false claims made within six years of the date of filing. The Act also permits assessment of the civil penalty even without proof of specific damages.
Rex Trailer Co. v. U.S., 350 U.S. 148 (1956).
7. Under the Act, a person ("relator") with knowledge of a false or fraudulent claim against the Government may bring an action against the false claimant on behalf of the Government and himself. Such an action must be filed under seal, without service on the defendant, for sixty days. The seal period is designed to permit the government to (1) pursue its own investigation of the matter without the defendant's knowledge of the suit and (2) determine whether to join and take over prosecution of the suit.

8. Pursuant to the requirements of 31 U.S.C. 3730(a)(2) and simultaneous with the filing of this complaint, Relator has provided a written statement of all material evidence in his possession to the U.S. Attorney General and the U.S. Attorney for the Western District of Missouri.
9. Defendants presented or caused to be presented claims for payment to the United States through its agent, the Department of Veterans Affairs, for plastic pharmaceutical bottles manufactured by defendant.
10. These claims for payment were fraudulent because the bottles provided in exchange for payment were in violation of statutory, regulatory, and/or contractual requirements and were invoiced on fraudulent cost of production.
11. Prescription bottles that do not comply with applicable standards place the Veterans using them in jeopardy as the medication contained in the bottles may be adulterated or degraded in quality thereby reducing or eliminating the medication's effectiveness.

FACTS COMMON TO ALL COUNTS

12. Since 1996, Defendant has contracted with the VA to provide pharmaceutical prescription bottles and caps.
13. The bottles provided to the VA were of three sizes: 120cc, 200cc and 250cc.
14. From 1996 until 2003, said bottles were manufactured from K-resin that was provided by Kraton Polymers ("Kraton") under contract with Defendant.
15. A known property of K-resin bottles is water absorption.

16. Defendant knowingly represented to the VA that the bottles they sold to the VA were in compliance with FDA standards for moisture absorption.
17. From 1999 through 2003, the vast majority of Prescription bottles manufactured by the Defendant failed pharmaceutical moisture tests.
18. Defendant had knowledge of the failed moisture tests.
19. Defendant sold these bottles to the VA despite the failed test, violating FDA standards for pharmaceutical bottles.
20. Defendant contracted with the VA to produce bottles in compliance with generally accepted production methods.
21. Defendant knowingly represented to the VA that the bottles they sold to the VA were manufactured in a manner consistent with generally accepted production methods.
22. Defendant incorporated “non-virgin” (also known as regrind) material into the Prescription bottles they sold to the VA.
23. In or around 1999, Defendant had approximately one and a half million bottles in the warehouse that had thin walls and pin holes that would not and/or had not passed the moisture test. These bottles were ground up and used as material to manufacture new bottles.
24. There are strict requirements governing the use of regrind in Prescription bottles.
25. Defendant incorporated said regrind material into the Prescription bottles in violation of generally accepted production methods.

26. Defendant incorporated said regrind material into the Prescription bottles after the bottles had been stored and/or shipped and/or prepared in a non-sterile environment.
27. Defendant knowingly represented a false “cost of manufacturing” quote in order to induce the VA to pay more than the Government would have, had it known the true cost of manufacturing.
28. Defendants received a material benefit (kickback) from Kraton during 2002 and 2003 for buying high volumes of resin. This benefit or “kickback” included a check for approximately \$120,000 to \$130,000 each of those two years.
29. This kickback was signed and approved by Tom Healy, the Executive Director of Alphapointe.
30. Defendant did not incorporate said kickbacks into their cost of manufacturing.
31. The costs to manufacture a 120cc bottle and 200cc bottle are 0.045736 [cents] and 0.067669 [cents] respectively.
32. Defendant contracted to sell the 120cc bottle for 0.15 [cents] per bottle and 0.21 [cents] per bottle for the 200cc bottle.
33. The United States, through the Department of Veterans Affairs, paid Defendant for these false and fraudulent claims.
34. In 2003, Defendant ceased producing bottles made of K-resin and began producing bottles made of “polypro.”

35. From 2003 until at least June 9, 2006, Defendant produced the “polypro” Prescription bottles using “regrind” in the same improper manner as described above.
36. Defendant has submitted fraudulent invoices and has received payment based on these fraudulent claims from the Department of Veterans Affairs from 1999 through at least June 9, 2006.
37. Plaintiff estimates that the Defendant has fraudulently invoiced and caused the United States of America to pay in excess of eight million dollars (\$8,000,000) and possibly up to the low to mid range of twenty to twenty-five million dollars \$20,000,000-\$25,000,000.

COUNT I - FALSE CLAIMS ACT
(Manufacturing Practices)

38. Plaintiff incorporates by reference paragraphs 1 through 37 as though fully set forth herein.
39. Prescription bottles are defined as a container closure system that contain and protect the dosage therein.
40. Prescription bottles should be suitable for their intended use and should adequately protect the dosage therein.
41. Prescription bottles containing mishandled “regrind” are not suitable for their intended use and do not adequately protect the dosages therein.
42. A container closure system should provide the dosage form with adequate protection from factors (e.g., temperature, light and moisture) that can cause a degradation in the quality of that dosage form over its shelf life. Common causes

of such degradation are: exposure to light, loss of solvent, exposure to reactive gases (e.g., oxygen), absorption of water vapor, and microbial contamination. A drug product can also suffer an unacceptable loss in quality if it is contaminated by filth.

43. Prescription bottles that do not provide adequate protection to the dosages therein can cause a degradation in the quality of the dosage form.
44. Prescription bottles that allow the absorption of water vapor or contain filth (i.e. improperly handled regrind) can cause a degradation in the quality of the dosage form.
45. Oral tablets should be packaged in a Prescription bottle that adequately protects it from light, water, temperature and filth
46. A drug or device shall be deemed to be adulterated "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health" (section 501(a)(3)); or "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess (section 501(a)(2)(B)).
47. Prescription bottles that do not comply with applicable standards place the Veterans using them in jeopardy as the medication contained in the bottles may be

adulterated or degraded in quality thereby reducing or eliminating the effectiveness.

48. By virtue of the false or fraudulent claims presented or caused to presented by the Defendant, the United States has suffered actual damages and is entitled to recover three times the amount by which it was damaged, plus civil money penalties of \$5,000 to \$10,000 for each of the false claims presented, plus attorney's fees and costs and for any and all other forms of relief allowed by law.

COUNT II - FALSE CLAIMS ACT
(Fraudulent Billing)

49. Plaintiff incorporates by reference paragraphs 1 through 48 as though fully set forth herein.

50. In addition to the aforementioned, Defendant submitted claims for payment and received payment based on improperly allocated manufacturing costs.

51. During the years of at least 2002 and 2003, Defendant received a financial kickback on k-resin used to manufacture their Prescription bottles, yet failed to apportion costs accordingly; thereby providing the VA with false data for the payment of claims.

52. These false claims were made knowingly.

53. By virtue of the false or fraudulent claims presented or caused to presented by the Defendant, the United States has suffered actual damages and is entitled to recover three times the amount by which it was damaged, plus civil money penalties of \$5,000 to \$10,000 for each of the false claims presented, plus attorney's fees and costs and for any and all other forms of relief allowed by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff United States of America respectfully prays for a trial by jury and the following relief: Judgment be entered in favor of Plaintiff and against Defendants for treble damages sustained by it, for civil money penalties of \$10,000 for each of the false claims presented or caused to be presented, plus interest, attorney's fees, costs, and any and all other relief allowed under law.

Respectfully submitted,
BROWN & ASSOCIATES, LLC

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